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Adopting a Complications Process

Aesthetics looks at the guidance available for practitioners when avoiding and reporting a complication

It's something that no practitioner ever wishes for, yet almost all will experience this during their medical careers: a complication. Complications can occur from all types of non-surgical aesthetic treatments including injectables, lasers and energy devices. Complications range from the mild, such as swelling and bruising, to the very severe and rare, such as vascular compromise. Whilst numerous training providers aim to provide adequate teaching in how to effectively and safely manage complications from a clinical perspective, many practitioners have different ways of ensuring they are prepared for an adverse event, recording the incidence and reporting the complication. In this article, *Aesthetics* explores the complications guidance available and practitioners provide their advice on recording and reporting adverse events.

Preparation

If a patient experiences a complication after leaving the clinic, will they know what to do and where to turn? This is one concern amongst practitioners, as there are many anecdotal instances of patients not informing the original practitioner of an adverse event, and instead, seeing their GP or going to their local A&E. "Patients *must* be equipped with comprehensive aftercare instructions," says aesthetic dentist Dr MJ Rowland - Warmann, who completed a dissertation on hyaluronic acid dermal filler complications as part of her Master's in Aesthetic Medicine. "Aftercare instructions should be given before the patient even has their procedure, as it is part of the initial consent process,"[1] she adds.

Dr Beatriz Molina, founder of the International Association for Prevention of Complications in Aesthetic Medicine (IAPCAM), says, "I have seen a huge increase in people walking into my clinic saying they were treated six or more months ago with a filler, they had a complication and didn't know what to do, so just 'put up with it'." She explains that one patient flew from Glasgow to her Somerset clinic, after the patient's GP recommended she see her. "The patient had spent nine months with bags under her eyes due to a superficial filler placement, and it was something that was easily corrected; she just didn't know what to do." As part of Dr Molina's work with IAPCAM, she is creating guidelines and instructions for both the patient and practitioner. "For the patient, instructions will say 'if things go wrong this is what to do' and the same for the practitioner," she explains.

What about complications that happen in clinic? You may be the most competent practitioner, but Dr Rowland-Warmann emphasises that you should always be prepared for an adverse event, "I'd recommend having an algorithm stuck to the inside of your cupboard door, because you may forget everything at a time of despair; whether it says: 'call this number for this complication' or 'do this, do that' it will help you stay collected and professional in front of the patient, which will help keep them calm."

Mr Dalvi Humzah, plastic reconstructive and aesthetic surgeon and founder of the Aesthetics Interventional Induced Visual Loss (AIIVL) Consensus Group, says, "I think practitioners should have an emergency handbook for all types of complications. They should have a step-by-step guide, that is unique to their clinic or clinical environment." He adds, "And what's most important, is that you must make sure the patient is fully informed as to what is happening and the pathway that you might be taking to deal with it."

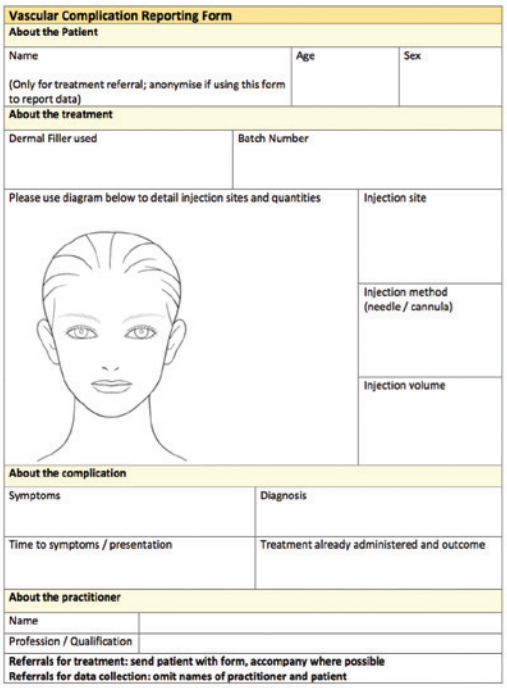
Support

Although all medical professional bodies, such as the General Medical Council (GMC), the Nursing and Midwifery Council (NMC), General Dental Council (GDC) and General Pharmaceutical Council (GPhC) would expect practitioners to know how to deal with a complication, there may be times when you need assistance and support, especially in particularly difficult and unique cases.[1,2,3,5] For example, the GPhC standards states, **"**Medical emergencies can happen at any time. You must make sure that there is at least one other person available within the working environment to deal with medical emergencies when you are treating patients." Dr Martyn King, chairperson of the Aesthetics Complications Expert (ACE) Group says, "If the complication is out of your depth, then clinically you are obliged to contact a more experienced practitioner or ask for help according to the GMC;[1] a lot of people will buddy up with somebody for this purpose." He adds, "From an ACE Group point of view, practitioners can go on the ACE Facebook forum and ask for some advice; if time's permitting. They can also contact the ACE Group directly and we will give them help and advice on how to manage it. Often, we can arrange a consultation and see the patient together."

Mr Humzah has concerns over practitioners getting the wrong advice from social media and unendorsed forums, so advises to use these with caution. He explains, "There is a vogue at the moment for going on the internet and talking in unofficial forums and that may not be the best way to deal with a complication as you may get conflicting advice." Dr King agrees, adding, "It depends how the forum is set up; there are a lot of forums that are quite derogatory. The difference with the ACE Group is that we have a professional forum which only allows discussions on complications, so anyone asking lots of questions on other matters or posting adverts get moderated quickly; we have zero tolerance. If you are going to use a forum it needs to be properly moderated." Dr King also notes that if you are asking for advice and potentially posting pictures onto a forum, you need to make sure you have the proper consent from the patient.[4]

Dr Molina says, "All practitioners should know how to deal with a complication, however, there are times where you might not be sure and you need the support of a practitioner, especially those who work on their own." She adds, "It is best to have a very good network of peers you can call on."

It is also important to build relationships with local hospitals in case of the rare occurance of a vascular compromise, according to Dr Rowland-Warmann. She says, "Firstly, stop, take stock of the situation and reassure the patient as it is going to be just as stressful for them as it is for you. Then, for an emergency such as vascular compromise, have a mentor you can call, have a local hospital number, and know where your local eye hospital is if a patient has suffered vision loss. It's also imperative to know exactly who to call at the hospital too for



Vascular Complication Reporting Form

About the Patient

Name (Only for treatment referral; anonymise if using this form to report data)	Age	Sex

About the treatment

Dermal Filler used	Batch Number

Please use diagram below to detail injection sites and quantities

Injection site

Injection method (needle / cannula)

Injection volume

About the complication

Symptoms	Diagnosis
Time to symptoms / presentation	Treatment already administered and outcome

About the practitioner

Name	
Profession / Qualification	

Referrals for treatment: send patient with form, accompany where possible
Referrals for data collection: omit names of practitioner and patient

Figure 1: Example of a vascular complication reporting form, created by Dr MJ Rowland-Warmann

emergencies such as these, as not everyone there will know how to specifically deal with aesthetic complications. Also, you should go with the patient to the hospital, to make sure they get the care they need."

Recording

Once the complication has been properly handled and dealt with, it is important for the practitioner to log and report it; minor side effects, such as bruising and minor swelling that resolves on its own, would not necessarily need to be reported, but the practitioner must use his or her discretion. Mr Humzah says, "You must ensure every detail is accurate and clearly recorded in your notes, it is very important for insurance purposes."[1-3,5] Dr Rowland Warmann says that as part of her clinic's Care Quality Commission (CQC) registration, they have an accident book where they log everything. She says, "You don't have to overcomplicate matters, just have one book where you can log everything. You need a protocol for reporting and logging so it doesn't get lost and that way you can audit all adverse events, no matter what they are." Information must be as detailed as possible, including all products used, batch numbers, any anaesthetic used and how the patient reacted.

Reporting

Reporting is essential practice for all medical practitioners and the GMC states that to help keep patients safe, practitioners should routinely monitor patient outcomes, and audit their practice, reporting at least annual data.[1] Practitioners are obliged by their governing bodies to report to the MHRA. Dr King adds, "Anyone who is a member of the ACE group can report it on the ACE website and we have a form that mirrors the MHRA one. Once we receive any filled-in forms, we forward them to the MHRA and the manufacturer of the product that was used."

Reporting to the MHRA

According to the GMC, you must inform the Medicines and Healthcare products Regulatory Agency (MHRA) about:[1]

- Serious suspected adverse reactions to all medicines and all reactions to products marked with a Black Triangle in the British National Formulary and elsewhere using the Yellow Card Scheme
- Adverse incidents involving medical devices, including those caused by human error that put, or have the potential to put, the safety of patients, healthcare professionals or others at risk

The NMC,[5] GDC[2] and GPhC[3] also obligate practitioners to report to the MHRA.[5] The GDC guidance states, "You must record all patient safety incidents and report them promptly to the appropriate national body."[2] The Yellow Card Scheme is described by the MHRA as vital in monitoring the safety of all healthcare products in the UK, 'to ensure they are acceptably safe for patients and those that use them'. Reports can be made for all medicines, including all medical devices available on the UK market such as dermal fillers. When reporting, you will need to fill out the short online form and provide the following:

- Name, position, organisation
- Address and contact details
- Device details
- Details of the incident

The Scheme collects information on suspected problems or incidents involving:

- **Side effects** (also known as adverse drug reactions or ADRs)
- **Medical device** adverse incidents
- **Defective medicines** (those that are not of an acceptable quality)
- **Counterfeit or fake** medicines or medical devices

The MHRA states, 'It is important for people to report problems experienced with medicines or medical devices as these are used to identify issues which might not have been previously known about. The MHRA will review the product if necessary, and take action to minimise risk and maximise benefit to the patients. The MHRA is also able to investigate counterfeit or fake medicines or devices and, if necessary, take action to protect public health'.[6]

For products and incidence that cannot be reported to the MHRA, practitioners interviewed for this article advise still to record it internally.

Reporting to the manufacturer

If it is a product-related complication then also refer it to the manufacturers, Mr Humzah says, "The more you tell manufacturers, the better. They can look at batch numbers, for example, and determine if a particular batch had a problem. But, unless you report it, they won't be able to tell you that."

Dr King explains that when reporting a complication to the MHRA, practitioners should include the manufacturer in the copy so that "these issues cannot be 'swept under the carpet' as the MHRA will issue a report number which cannot be ignored so easily."

Dr King is concerned that some practitioners are not reporting to the manufacturers, due to concerns over repercussions. "People shouldn't fear reporting; I think some believe that if they report a complication with a certain product to the manufacturer, then the manufacturer will get upset and stop visiting them or inviting them to conferences. But, in the same way as the NHS does, we need to be open and if there are problems we need to report them. The MHRA doesn't tend to act on single, one-off reports, but if it gets 10-20 reports of the same product, its team will think 'there is a problem here' and action it," he advises. Manufacturers must encourage reporting, and according to Dr King, legally they have to have some mechanism to report, however, he says, "these are often not very transparent, and are

without a rigorous process."
As for the details that should be included, he says "Sex and age are permitted as non-traceable but a patient identification number is needed in case the reporting leads to legal proceedings whereby a court can request disclosure."

Reporting to insurance providers

If you have a complication, do you tell your medical defence/malpractice insurer, and at what point do you do so? "Thankfully, you see quite a lot of complications that are so well managed, with the patients kept on-board, that very few turn into complaints," says Dr King; however, he notes, "Still ensure you document everything accordingly in case they do complain as you will need to provide the insurer with this information."
Mr Humzah adds, "If your patient has a complication, you have to consider your insurance company straight away. Check your policy, as insurance providers have different requirements of what to inform them of. Some may say only inform them if it is something that is definitely going to become a legal issue, others say you should inform them of *all* complications, even if it is not likely to proceed to something legal."
Sharon Allen, business development executive at Enhance Insurance explains in more detail, "When a practitioner comes face-to-face with a situation where their patient isn't happy with their results or suffers an adverse reaction to a treatment or procedure provided, it can be very daunting and distressing. It is at this time practitioners need to contact their broker, advising them of the situation, who in turn notify insurers."
Allen explains that a majority of incidents are logged for 'notification purposes only' and after a while will be closed. Depending on the circumstances, a draft response may initially be issued for the practitioner to send to their patient, to try and minimise the situation and stop the incident escalating into a claim. In some cases, a refund of the treatment cost will also be offered. "Either way," says Allen, "it is imperative insurers are notified as soon as possible, failure to do so may jeopardise the claim or result in the practitioner not complying with a policy clause, resulting in the insurer not providing indemnity. If unsure, I recommend practitioners contact their broker so that they fully understand their obligations."
Allen advises that the majority of medical malpractice policies are written on a 'claims made' basis, meaning that "it is the policy in force at the time the complaint/notification is made who will deal with the matter, regardless of the policy in force at the time of the incident. "She adds, "If the practitioner was aware of a situation within the previous policy period and had not contacted their insurer at the time, then the new or existing insurer will not indemnify them and the practitioner may have to deal with the matter themselves."

Lack of data

Due to a lack of reporting, data on complications in medical aesthetics is minimal, and this is something all the practitioners interviewed want to see change.
Dr King acknowledges that reporting is very poor, "On the ACE Facebook forum, we probably get a complication mentioned every day, but officially, there is only one reported on our website every three to four weeks. If you are reporting quite a few complications, then I think the practitioner might be worried there will be repercussions on them. But complications happen."
Mr Humzah adds, "People do get embarrassed but they've got to get over that. It is all about the learning process and sharing that complication for other people to learn and prevent it from happening to someone else."
This is something Dr Molina wants to ensure, and is currently looking into ways to do this. She says, "I am setting up an audit process with IAPCAM, which will include all medical practitioners who are registered and authorised to perform treatments. They can report complications with us and we will collect the data and share it. At the moment, even if I report a complication to a manufacturer, then no one else will find out about it, only the company. We all need to be able to see the issues."

Improving the process

Each of the practitioners interviewed for this article believe more needs to be done to improve the process of handling, recording and reporting complications.
Although aesthetic practitioners would recommend patients return to see them if they have a complication, many patients turn up at their GP surgery or local A&E, thinking that is the best place to go. However Dr Molina argues that the NHS is not the best place for patients to seek a resolve. Dr Molina says, "With IAPCAM, we would like to set up some guidelines and send them to places such as A&E and GP surgeries, as at the moment, when patients turn up there, they are getting lots of different advice."
According to Dr Rowland-Warmann, training providers need to ensure they are equipping practitioners, "Training course providers should think about how they teach trainees on complication management. Practitioners who I mentor have said to me that if a complication occurred they wouldn't know how to deal with it. They have said that the use of hyaluronidase was 'glossed over' and they didn't know about any other complications except ones with HA filler."
Dr Molina emphasises, "Know your anatomy, then learn complications, then learn to inject. You shouldn't be injecting unless you know how to deal with the complication, so I think that should be taught first."
Dr King says, "I think there needs to be a *lot* more done, and it needs to come from the professional bodies, such as the GMC and GDC, or the MHRA. More emphasis should be made on the importance of knowing what to do when faced with a complication. I think manufacturers and suppliers have a duty to help practitioners and make it easy to report to them."
He concludes, "The MHRA forms are so easy to fill out, and take just two minutes. In terms of procedure and policy, I would say make sure you write down as much information as possible, including batch numbers and expiry dates. It is all about documentation; it has to be done at the time, and be completely accurate."

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